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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,988	09/24/2001	Jeffrey Schlom	2026-4292US1	7849

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,988	SCHLOM ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,89-93 and 107-131* is/are pending in the application.

4a) Of the above claim(s) *128 and 131* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,89-93,107-127,129 and 130* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *128 and 131* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 37, 89-93 and 107-131 are pending before the examiner.

Election/Restrictions

Newly submitted claims 128 and 131 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original elected group of invention is directed to a host cell comprising a vector encoding multiple co-stimulatory factors and an antigen. But the vector does not encode a cytokine that are claimed in claims 128 and 131.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim131 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

1. This is a response to the amendment, paper No. 21, filed 08/04/03. Claims 37, 89 and 91 have been amended. New claims 107-131 are added.

2. Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

3. Claims 89-93 and 129-130 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action.

4. Applicants argue that the specification of current application contains a wealth of data showing the effectiveness of claimed invention, in particular, examples 24-33. Applicants further asserted the examiner has not addressed this data.

5. Applicants' argument has been fully considered; however, it is not found persuasive because examples of 24-33 do not provide the data that support that the claimed a host cell comprising the vector, and a method for using the host cell are able for preventing any or all

disease as listed in the rejected claims in an ex vivo model. Therefore, the rejection is maintained unless applicant amend the claims to deletion the recitation of prevention of a disease.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

7. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

8. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 37 and 107-126 are still rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 6 of U.S. Patent No. 6,548,068 on the same ground as stated in the previous Office Action.

10. Applicants argue that examiner must indicate how the claims of the instant application are sufficiently "obvious" over the other claims so as to result in an impermissible prolongation of parent term. The examiner, however, has not made out a prima facie case why the claims are obvious in view of one another, and therefore the rejection should be withdrawn.

11. Applicants' argument has been respectfully considered; however, it is not found persuasive because patent "068" is directed to a host cell infected with a recombinant viral vector , in particular a recombinant vaccinia viral vector, comprising multiple costimulatory molecules, such as B7.1, and B7.2, optionally with another immunostimulatory molecule, such as ICAM-3, LFA-3 and a tumor associated antigen, preferably ECA. Furthermore, it also teaches that after

about 1-16 hours ex vivo treatment, the activated host T lymphocytes are administrated to mammal for treatment of cancer and the treatment may be administrated concurrently with other cytokine (lines 3-16 on col. 30). Therefore, it would have been obvious for any person with ordinary skill in the art to make a composition comprising a recombinant vector that carries the co-stimulatory molecules and an antigen as disclosed by patent "068" to infect a host cells for producing an enhanced immune response by using the same. Because claims 37 and 107-126 are directed to a same composition for producing an enhanced immune response. While the current application is directed to a generic recombinant vector, and Patent "068" is specifically directed to use a particular vaccinia vector for carrying the co-stimulatory factors, the species of a vaccinia viral vector is in the scope of a generic recombinant vector. Hence the scope of claimed invention is overlapping.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 37 is still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Hargraves et al. (International Immunology 1995, Vol. 7, pp. 1505-1513).

13. Applicants argue that Hargreaves et al. only teach that transfected cells express B7 and one other MHC class II alloantigen. Accordingly, hargreaves et al. cannot anticipated the claim.

14. Applicants' argument has been fully considered; however, it is not found persuasive because Hargreaves et al. disclose a mouse B7-expression DAP.3/DR host cell line is supertransfected with cDNA clones encoding human ICAM-1 and/or human LFA-3 respectively (See lines 14-35 on 1st col. of page 1512), wherein the cDNA clones are CDM8 recombinant vector and pcEXV-3 recombinant vector. Therefore, the claimed invention is anticipated by the cited reference.

New Ground of Rejection:

Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 107-120 and 122-125 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention directed to a host call infected, transfected or induced by a recombinant vector that comprising sequences encoding B7, ICAM-1 and LFA03as well as any of all antigen as listed in claims 107-120 and 1220125 except the antigen CEA.

17. In the instant disclosure, the applicants have only disclosed a host cell comprising a vector encoding co-stimulatory factors B7, ICAM-1 and LFA-3 and CEA antigen. Therefore, a written description of the other claimed host cells comprising a vector encoding B7, ICAM-1 and LFA-3 and any or all antigen as listed in claims 107-120, 122-125 except ECA cancer gene should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that "a patent specification contain a written description of the invention and the manner and process of making and using it in such full clear and concise terms as to enable one skilled in the art to make and use the invention". Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular host cells because it gives detailed information on how to produce analogous host cells but it makes no reference to the host cells in question,

the "written description" requirement has not been met even though the description may be enabling.

Conclusion

No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
October 01, 2003

James C. Housel 10/20/03

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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